



Natural Dairy Products Corporation

PO Box 464

West Grove, PA 19390

Phone: (610) 268-6962

1 NOSB CFR 184 1545

DIRECT/GRAS

June 20, 2002

Toni Strother NOP 1400 Independence Avenue SW Rm. 4008 South Ag. Stop 0268 Washington, DC 20250

Dear Toni:

We would like to petition the addition of Nitrous Oxide as a Whipping Propellant to the National Substances Allowed in Organic Production Handling.

The nitrous oxide is in the following category:

Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)".

- 1. Substance's common name: Nitrous Oxide
- 2. Manufacturer's Name, address, and telephone #: Nitrous Oxide Corp., 259 N. Radnor Chester Rd. Suite #100, Radnor, PA 19087. 610-902-6248
- 3. The intended or current use of the substance is as a whipping propellant for Organic Whipped Cream.
- 4. N/A
- 5. Source of the substance-The source of the product is from Pensacola, FL or Yazoo City, Mississippi. Nitrous Oxide is made by the decomposition of ammonium nitrate and by separation from adipic acid off gas.
- 6. Quality Assurance International is in process of certifying the Whipped Cream and can not proceed until we get approval for the nitrous oxide.
- 7. FDA Labeler code- 054260
- 8. CAS # 10024 97 2
- 9. An MSDS is included as well as a Specification Sheet, aka a Technical Bulletin.

Enclosed, please find back-up information from the Nitrous Oxide Company regarding this product. I look forward to hearing from you regarding this matter. If you should require any further information, please contact me at 610-268-6962.

Sincerely, Christy Manger [Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR184.1545]

[Page 526]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEAL' SERVICES (CONTINUED)

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECO

Subpart B--Listing of Specific Substances Affirmed a

Sec. 184.1545 Nitrous oxide.

- (a) Nitrous oxide (empirical formula N<INF>2</INF>0, CA 10024-97-2) is also known as dinitrogen monoxide or laughing a colorless gas, about 50 percent heavier than air, with a sweet smell. It does not burn but will support combustion. It manufactured by the thermal decomposition of ammonium ni oxides of nitrogen are removed by passing the dry gas through scrubbing towers.
- (b) The Food and Drug Administration is developing food specifications for nitrous oxide in cooperation with the Na Academy of Sciences. In the interim, the ingredient must be suitable for its intended use.
- (c) In accordance with Sec. 184.1(b)(1), the ingredient food with no limitations other than current good manufactur. The affirmation of this ingredient as generally recognized (GRAS) as a direct human food ingredient is based upon the current good manufacturing practice conditions of use:
- (1) The ingredient is used as a propellant, aerating ag as defined in Sec. 170.3(o)(25) of this chapter.
- (2) The ingredient is used in dairy product analogs as Sec. 170.3(n)(10) of this chapter at levels not to exceed comanufacturing practice.
- (d) Prior sanctions for this ingredient different from established in this section do not exist or have been waive

[48 FR 57270, Dec. 29, 1983]

lirgas

12 21 MG

June 11, 2002

Airgas Nitrous Oxido 259 N. Radnor-Chester Rd., Suite 100 Radaey, PA 19087-5283 (610) 902-6248 Fac (610) 225-3273 www.airgas.com

Mr. Thomas Pritchard Alamance Dairy 739 S. Worth St. Burington, NC 27216

Dear Mr. Pritchard:

Pursuant to your request by fax dated June 3, 2002, I wanted to provide written confirmation of our responses. I will take them in the order they are presented in the fax. numbered from 1-12.

- 1. Nitrous Oxide
- 2. Nitrous Oxide Corp., 259 N. Radnor Chester Rd. Suite # 100, Radnor, PA 19087.
- 3. The intended use is as a food additive
- 4. Do not know the answer to this question, should be provided by Alamance Dairy
- 5. The source of the product is from Pensacola, Florida or Yazoo City, Mississippi. Nitrous Oxide is made by the decomposition of ammonium nitrate and by separation from adipic acid off gas.
- 6. N/A
- 7. FDA labeler code 054260
- 8. CAS # 10024 97 2
- 9. An MSDS is included as well as a Specification Sheet, aka a Technical Bulletin.
- 10. We are not familiar with a 'substance report' from the National Institute of Environmental Health Studies.
- 11. We are not clear on how to respond to this question, or to question # 12. The reason why? "which present contrasting positions to those presented by the patitioner in supporting the substance's inclusion on or removal from the National List. NOC is not familiar with such a report.

15. REGULATORY INFORMATION (Continued)

Close valve after each use and when empty

Use in accordance with the Material Safety Data Sheet.

NOTE:

Suck-back into cylinder may cause rupture.

Always use a back flow preventative device in piping.

FIRST AID:

IF INHALED, remove to fresh air. If not breathing, give artificial respiration. If breathing is

difficult, give oxygen. Call a physician.

IN CASE OF FROSTBITE, obtain immediate medical attention. DO NOT REMOVE THIS PRODUCT LABEL.

ADDITIONAL CANADIAN REGULATIONS: -

CANADIAN DSL/NDSL INVENTORY STATUS: Nitrous Oxide is on the DSL Inventory.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITY SUBSTANCES LISTS: This compound is

not on the CEPA Priority Substances Lists.

CANADIAN WHMIS SYMBOLS:

Class A: Compressed Gases

Class C: Oxidizing Materials

Class D2A: Materials Causing Other Toxic Effects







16. OTHER INFORMATION

PREPARED BY:

Alrgae - SAFECOR

The information contained herein is based on data considered accurate. However, no warrenty is expressed or implied regarding the accuracy of these data or the results to be obtained from the use thereof. AIRGAS, Inc. assumes no responsibility for injury to the vendee or third persons proximately caused by the meterial if reasonable safety procedures are not adhered to as attpulated in the data sheet. Additionally, AIRGAS, inc. assumen no responsibility for injury to vendee or third persons proximately caused by abnormal use of the material even if reasonable salety procedures are followed. Furthermore, vendee assumes the risk in his use of

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Thomas, should there be additional inquiries, please do not hesitate to direct them to me. I hope the above clarifies and informs you the information you desire.

Sincerely,

Jeff Clay

National Marketing

Manager

c: Ron Scott - President Nitrous Oxide Corp Martin Tupman - Nitrous Oxide Corp. Engineer Richard A. Lake - President National Welders

Enclosures: NOC MSDS dated 01/02/02, NOC Technical Bulletin dated 01/01/95

ALAM1867

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION: Epidemiological studies suggest feto-toxic effects and higher rates of spontaneous abortions in personnel who have been over-exposed to Nitrous Oxide. Although a definite causal relationship between Nitrous Oxide exposures and reproductive problems has not been established, exposure to the gas should be minimized. Listed below is additional information concerning the effects of Nitrous Cxide on the human reproductive system

Mutagenicity: Nitrous Oxide is not expected to cause mutagenic effects in humans.

Embryotoxicity: Nitrous Oxide is reported to cause embryotoxic effects in laboratory animals.

Teratogenicity: Nitrous Oxide may cause teratogenic effects in humans. Exposure to Nitrous Oxide has caused embryo and fetal toxicity effects in laboratory animals. Such offects include reduced fetal weight, delayed ossification, and an increased incidence of visceral and skeletal variations.

Reproductive Toxicity: Nitrous Oxide may cause adverse reproductive effects in humans.

A mutagen is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An embryotoxin is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance which interferes in any way with the reproductive process.

BIOLOGICAL EXPOSURE (NDICES (BEIs): Currently, Biological Exposure Indices (BEIs) have not been determined for Nitrous Oxide.

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL STABILITY: The gas will be dissipated rapidly in well-ventilated areas.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: Any adverse effect on animals would be related to oxygen deficient environments, effects on the central nervous system, and potential reproductive problems. Symptoms of exposure would be similar for those described for humans. No adverse effect is anticipated to occur to plant-life, except for frost produced in the presence of rapidly expanding gases.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No evidence is currently available on the effects of Nitrous Oxide on aquatic life. This gas is soluble in water.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Product removed from the cylinder must be disposed of in accordance with -appropriate Federal, State, and local regulations. Return cylinders with residual product to Airgas. Do not dispose of locally.

14. TRANSPORTATION INFORMATION

THIS MATERIAL IS HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

For Nitrous Oxide Gas:

PROPER SHIPPING NAME:

Nitrous oxide

HAZARD CLASS NUMBER and DESCRIPTION:

2.2 (Non-Flammable Gas)

UN IDENTIFICATION NUMBER:

UN 1070

PACKING GROUP:

Not Applicable

DOT LABEL(S) REQUIRED:

Non-Flammable Gas, Oxidizer

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2000): 122

For Nitrous Oxide, Refrigerated Liquid:

PROPER SHIPPING NAME:

Nitrous oxide, refrigerated liquid

HAZARD CLASS NUMBER and DESCRIPTION:

2.2 (Non-Flammable Gas)

UN IDENTIFICATION NUMBER:

UN 2201

PACKING GROUP:

Not applicable.

DOT LABEL(S) REQUIRED:

Non-Flammable Gas, Oxidizer

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2000): 122

MARINE POLLUTANT: Nitrous Oxide is not classified by the DOT as a Marine Pollutant (as defined by 49 GFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: THIS MATERIAL IS CONSIDERED AS DANGEROUS GOODS. Use the above information for the preparation of Canadian Shipments.

Airgas.

TECHNICAL BULLETIN NO. IT-NOC-3 EFFECTIVE: 4/1/92

REVISED: 1/1/95

Corporate Office: 259 N. Radnor-Chester Road • Suite 100 • P.O. Box 6675 • Radnor, PA 19087-5283 • (610) 902-6248

NITROUS OXIDE - N2O

Nitrous Oxide is a colorless, non-flammable, non-toxic gas with a slightly sweet taste and odor. Nitrous Oxide is produced by controlled thermal decomposition of high purity ammonium nitrate. The gas is then purified, compressed and liquified for storage and shipment.

USES

Nitrous Oxide is used mainly as an inhalation anesthetic. It is a rather weak anesthetic and must be inhaled in fairly high concentrations mixed with air or oxygen.

Other uses are as a propellant for food grade aerosols, a refrigerant, a leak detecting agent, an oxidizing agent, a chemical reagent, an ingredient in fuel combinations, and, in highly purified form, as a plasma etching chemical for semiconductor manufacturing.

SPECIFICATIONS:

The standard grade produced by Nitrous Oxide Corp. conforms to the testing and quality requirements of the U.S. Pharmacopeia XXIII dated, January 1, 1995. (U.S.P. Grade)

Nitrous Oxide (N2O)	99.0%	v/v	(liquid)	Minimum
Carbon Monoxide (CO)	10 ppm	v/v	(vapor)	Maximum
Nitric Oxide (NO)	1 ppm	v/v	(vapor)	Maximum
Nitrogen Dioxide (NO2)	l ppm	v/v	(liquid)	Maximum
Halogens (measures as CI2)	1 ppm	v/v	(vapor)	Maximum
Carbon Dioxide (CO2)	300 ppm	\mathbf{v}/\mathbf{v}	(vapor)	Maximum
Ammonia (NH3)	25 ppm	v/v	(vapor)	Maximum
Water (H2O)	150 mg/m3	v/v	(vapor)	Maximum

Higher purities are available for special applications.

7. HANDLING and STORAGE (Continued)

Do not store containers where they can come into contact with moisture. Cylinders should be stored upright and be firmly secured to prevent falling or being knocked over. Cylinders can be stored in the open, but in such cases, should be protected against extremes of weather and from the dampness of the ground to prevent rusting. Never tamper with pressure relief devices in valves and cylinders. The following rules are applicable to cylinder use:

Before Use: Move cylinders with a suitable hand-truck. Do not drag, slide or roll cylinders. Do not drop cylinders or permit them to strike each other. Secure cylinders firmly. Leave the valve protection cap, if provided, in-place until cylinder is ready for use.

During Use: Use designated CGA fittings and other support equipment. Do not use adapters. Do not heat cylinder by any means to increase the discharge rate of the product from the cylinder. Use check valve or trap in discharge line to prevent hazardous backflow into the cylinder. Do not use oils or grease on gas-handling tittings or equipment.

After Use: Close main cylinder valve. Replace valve protection cap, if provided. Mark empty cylinders "EMPTY".

NOTE: Use only DOT or ASME code containers. Close valve after each use and when empty. Cylinders must not be recharged except by or with the consent of owner. For additional information refer to the Compressed Gas Association Pamphlet P-1, Safe Handling of Compressed Gases in Containers. Additionally, refer to CGA Bulletin SB-2 "Oxygen Deficient Atmospheres".

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: Follow practices indicated in Section 6 (Accidental Release Measures). Make certain application equipment is locked and tagged-out safety. Purge gas handling equipment with inert gas (e.g., nitrogen) before attempting repairs.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

<u>VENTILATION AND ENGINEERING CONTROLS</u>: Use with adequate ventilation. Local exhaust ventilation is preferred, because it prevents Nitrous Oxide dispersion into the work place by eliminating it at its source. If appropriate, install automatic monitoring equipment to detect the level of oxygen or Nitrous Oxide.

RESPIRATORY PROTECTION: Maintain oxygen levels above 19.5% In the workplace and below the exposure limits listed in Section 2 (Composition and Information on Ingredients). Use supplied air respiratory protection if oxygen levels are below 19.5% or during emergency response to a release of Nitrous Oxide. If respiratory protection is required, follow the requirements of the Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), applicable State regulations, or the Canadian CSA Standard 294.4-93 and applicable standards of Canadian Provinces. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).

EYE PROTECTION: Splash goggles, face-shields or safety glasses. Face-shields must be worn when using liquid Nitrous Oxide.

HAND PROTECTION: Wear mechanically-resistant gloves when handling cylinders of Nitrous Oxide. Use low-temperature protective gloves (e.g. Kevlar) when in situations in which splashes of liquid Nitrous Oxide may occur.

<u>BODY PROTECTION</u>: Use body protection appropriate for task. Transfer of large quantities under pressure may require protective equipment appropriate to protect employees from splashes of liquefied product, as well provide sufficient insulation from extreme cold.

9. PHYSICAL and CHEMICAL PROPERTIES

VAPOR DENSITY: 1.947kg/m3 (0.115 lb/ft3)

SPECIFIC GRAVITY (air = 1): 1.530

SOLUBILITY IN WATER: Soluble.

VAPOR PRESSURE (psia): 759.7

EXPANSION RATIO: Not applicable.

COEFFICIENT WATER/OIL DISTRIBUTION: 0,665

EVAPORATION RATE (nBuAc = 1): Not applicable.

FREEZING POINT: -90.9°C (-131,5°F)

BOILING POINT(°F @ 1 atm): -88.5°C (-127.4°F)

pH: Not applicable.

ODOR THRESHOLD: Not determined.

SPECIFIC VOLUME (17/10): 8.7

<u>APPEARANCE AND COLOR</u>: Nitrous Oxide is a colorless gas or a colorless liquid. Both the liquid and gas have a sweet odor.

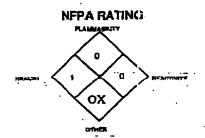
HOW TO DETECT THIS SUBSTANCE (warning properties): There are no unusual warning properties associated with a release of Nitrous Oxide. In terms of leak detection, filtings and joints can be painted with a soap solution to detect leaks, which will be indicated by a bubble formation.

Airgas

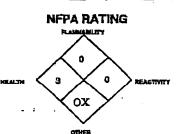
MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI and Canadian WHMIS Standards

NITROUS OXIDE GAS



NITROUS OXIDE REFRIGERATED LIQUID



PART I

What is the material and what do I need to know in an emergency?

1. PRODUCT IDENTIFICATION

CHEMICAL NAME: CLASS:

NITROUS OXIDE - N2O NITROUS OXIDE - N2O (Refrigerated Liquid)

PRODUCT USE:

Document Number: 001042 For use in anesthesia and general

analytical/synthetic chemical applications.

SUPPLIER/MANUFACTURER'S NAME:

AIRGAS INC.

ADDRESS:

259 N. Radnor-Chester Road

Suite 100

Radnor, PA 19087-5283

BUSINESS PHONE: EMERGENCY PHONE: 1-610-687-5253 1-800-949-7937

International: 423-479-0293 (Call Collect)

DATE OF PREPARATION:

May 20, 1996

REVISION DATE:

January 2, 2002

2. COMPOSITION and INFORMATION ON INGIREDIENTS

CHEMICAL NAME	CAS#	mole %	EXPOSURE LINITS IN AIR					
			ACGIH		OSHA			
			TLV	STEL	PEL	STEL.	NOTH	OTHER
			bbw	ррп	bbij	ppm	ppm	
Nitrous Oxide	10024-97-2	> 99.0%	50, A4 (Not Classifiable as a Human Carcinogen)	NE	NE	NE	NE	NIOSH REL: 25 ppm DFG MAK: 100 ppm
Maximum Impurities < 1.0%		None of the trace impurities in this mixture contribute significantly to the hezards associated with the product. All hazard information pertinent to this product has been provided in this Material Safety Data Sheet, par the requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200) and State equivalent standards.						

NE - Not Established

C = Ceilling Limit

See Section 16 for Definitions of Terms Used

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1-1993 format.

3. HAZARD IDENTIFICATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS: Contact with liquid or rapidly expanding gases (which are released under high pressure) may cause frostbite. Symptoms of frostbite include change in skin color to white or grayish-yellow. The pain after contact with liquid can quickly subside.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lav Terms. Overexposure to Nitrous Oxide may cause the following health effects:

ACUTE: The most significant hazard associated with this gas is inhalation of oxygen-deficient atmospheres and effects on the central nervous system. Symptoms of oxygen deficiency or central nervous system depression include respiratory difficulty, ringing in ears, headaches, dizziness, indigestion, and nausea. At high concentrations, unconsciousness or death may occur. Contact with liquid or rapidly expanding gases may cause frostbite.

CHRONIC: Prolonged or repeated overexposures to Nitrous Oxide has produced injury to the nervous system. Symptoms of such overexposure include numbness, tingling of the hands and legs, loss of feeling in the fingers, and muscular weakness. Exposure to Nitrous Oxide may be associated with an increase in spontaneous abortions in humans. Single, prolonged exposures to Nitrous Oxide have resulted in bone marrow damage and adverse effects on the blood. Refer to Section 11 (Toxicological Information) of this MSDS for additional information.

TARGET ORGANS: Respiratory system, central nervous system, blood system, reproductive system.

PART II

What should I do if a hazardous situation occurs?

4. FIRST-AID MEASURES

RESCUERS SHOULD NOT ATTEMPT TO RETRIEVE VICTIMS OF EXPOSURE TO NITROUS OXIDE WITHOUT ADEQUATE PERSONAL PROTECTIVE EQUIPMENT. At a minimum, Self-Contained Breathing Apparatus and Personal Protective Equipment should be worn.

Remove victim(s) to fresh air, as quickly as possible. Trained personnel should administer supplemental oxygen and/or cardio pulmonary resuscitation, if necessary. Only trained personnel should administer supplemental oxygen.

In case of frostbite, place the frostbitten part in warm water. DO NOT USE HOT WATER. If warm water is not available, or is impractical to use, wrap the affected parts gently in blankets. Alternatively, if the fingers or hands are frostbitten, place the affected area in the armpit. Encourage victim to gently exercise the affected part while being warmed. Seek immediate medical attention.

Victim(s) must be taken for medical attention. Rescuers should be taken for medical attention, if necessary. Take copy of label and MSDS to physician or other health professional with victim(s).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing respiratory conditions, central nervous system disorders, blood and immune system disorders, and pregnancies may be aggravated or adversely effected by overexposure to Nitrous Oxide.

RECOMMENDATIONS TO PHYSICIANS: Provide oxygen, treat symptoms, and reduce overexposure.

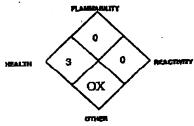
5. FIRE-FIGHTING MEASURES

NITROUS OXIDE GAS

NFPA RATING 0 HEALTH OX

NITROUS OXIDE REFFIGERATED LIQUID





See Section 16 for Definition of Batings

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS (in air by volume, %):

Lower (LEL): Not applicable. Upper (UEL): Not applicable.

NITROUS OXIDE- N2O MSDS (Document # 001042) PAGE 3 OF 10